K081234

Section 5:

JUL 14 2008

510(k) Summary

Date:	April 30, 2008
Submitted By:	GN Otometrics 125 E. Commerce Drive Schaumburg, IL 60173 USA
Telephone: **Fax:**	847-534-2150 x 6932 847-534-2153
Contact Person:	Daniel Sansonetti Manager of Research & Development dsansonetti@gnotometrics.com
Name of Device:	OtoInsert
Common Name:	Insert Earphones for auditory stimulus delivery
Classification Name:	Accessories to devices with classification: Audiometer (per 21 CFR section 874.1050) and Accessories to devices with classification: Stimulator, Auditory, Evoked Response, (per 21 CFR section 882.1900)
Predicate Device:	Etymotic Research ER-3 Insert Earphones, 510(k) #K930003

K081234

510(k) Submission (21 CFR 807.90(e)) for GN Otometrics Insert Earphones

Description of the Device:

The GN Otometrics Insert Earphones are transducers that convert electrical stimulus, provided by GN Otometrics Audiometers and GN Otometrics Auditory Evoked Response Stimulators, into acoustic stimulus, which is then coupled to the patient's ears. They are comprised of five sections: 1.) Electrical Transmission Path, 2.) Electrical Filter, 3.) Speaker, 4.) Acoustic Transmission Path, and 5.) Transducer Case.

The Electrical Transmission Path consists of a shielded cable. The cable is connected to the Audiometer or Auditory Evoked Response Stimulator, by means of a connector. The other end of the cable is attached to the left and right Electrical Filter Sections.

Each Electrical Filter section (left and right) consists of a passive analog filter to provide electrical pre-emphasis response shaping to the stimulus prior to reaching the Speakers.

Each Speaker (left and right) converts the electrical stimulus into an acoustic stimulus. The acoustic stimulus is delivered to the patient's ear by means of the Acoustic Transmission Path.

Each Acoustic Transmission Path (left and right) consists of a front acoustic transmission path and a back acoustic transmission path. The back acoustic transmission path consists of a series of tubes and cavities which are configured to create two resonant acoustic circuits. These resonant circuits are used to smooth the acoustic output at the eartip, by reducing the primary and secondary resonant peaks caused by the impedance mismatch at both ends of the front transmission path. The front acoustic transmission path consists of silicon tubing, tube nipple, and an eartip. The tube nipple provides acoustic and mechanical connection to the disposable eartip. The disposable eartips interface to the patient's ear and deliver the acoustic stimulus.

Each Transducer Case (left and right) houses an Electrical Filter, Speaker, and back acoustic transmission path. Each Transducer case provides means of handling and labeling and means to secure the Electrical Transmission Path (cable).

Intended Use of the Device:

The GN Otometrics Insert Earphones are accessories to the GN Otometrics Audiometers and GN Otometrics Auditory Evoked Response systems. The GN Otometrics Insert Earphone devices perform as the means for delivering auditory stimulus to the ears of the patient under test. The interface to the ears of the patient is provided by means of disposable foam eartips, designed to fit infants, children, and adults.

Comparison to Predicate Device:

The GN Otometrics Insert Earphones were designed to be a direct replacement to the Etymotic Research ER-3 Insert Earphones (510(k) #K930003). The GN Otometrics Insert Earphones share the same technological characteristics as the Etymotic Research ER-3 Insert Earphones (510(k) #K930003). Both insert earphones are comprised of the same sections: 1.) Electrical Transmission Path, 2.) Electrical Filter, 3.) Speaker, 4.) Acoustic Transmission Path, and 5.) Transducer Case.

The Electrical Transmission Path in both the GN Otometrics and Etymotic Insert Earphones are comprised of a cable with a connector on each end. The only differences are cable manufacturer, cable color, durometer, nominal dimensions, and connector type.

The Electrical Filter sections of both the GN Otometrics and Etymotic Insert Earphones are identical with respect to component values and configuration. The only difference is component manufacturers.

The Speaker in both the GN Otometrics and Etymotic Insert Earphones are from the same manufacturer and are the same model number.

The Acoustic Transmission Path in both the GN Otometrics and Etymotic Insert Earphones are identical with respect to nominal dimensions and configuration. Both the GN Otometrics and Etymotic Insert Earphones have a front and back acoustic transmission path. The only difference in the back transmission path is the material and construction method. The Etymotic Insert Earphones use PVC tubing to create the acoustic resonant circuits, while the GN Otometrics uses stainless steel tubes inserted into a rubber molded part. The end result of both construction methods is the same. The front transmission path is identical with respect to materials, dimensions, and coupling means to the patient. Both the GN Otometrics and Etymotic Insert Earphones use the same disposable eartips from the same manufacturer.

The Transducer Case in both the GN Otometrics and Etymotic Insert Earphones are similar with exception to shape and color.

The intended use of both the GN Otometrics and Etymotic Insert Earphones is the same. Both the GN Otometrics and Etymotic Insert Earphones are intended to be used as transducers to convert electrical stimulus, delivered by an Audiometer or Evoked Potential stimulator, into acoustic stimulus, which is then delivered to the patient's ear by means of a disposable Eartip.

Substantial Equivalence Performance Metrics:

Substantial equivalence to the Etymotic Research ER-3 Insert Earphones (510(k) #K930003) was based on non-clinical performance testing of the acoustic and electrical parameters as specified in the ANSI/ASA S 3.6-2004, Specification for Audiometers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2008

GN Otometrics
c/o Daniel Sansonetti
Manager of Research & Development
125 E. Commerce Drive
Schaumburg, IL 60173

Re: K081234
Trade/Device Name: GN Otometrics Insert Earphones
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: June 27, 2008
Received: June 27, 2008

Dear Mr. Sansonetti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081234

Section 4:

Indications for Use

510(k) Number (if known): K081234

Device Name: GN Otometrics Insert Earphones

Indications for Use:

The **GN Otometrics Insert Earphones** are accessories to the GN Otometrics Audiometers and Chartr EP Auditory Evoked Response systems. The **GN Otometrics Insert Earphones** devices perform as the means for delivering auditory stimulus to the ears of the patient under test. The interface to the ears of the patient is provided by means of disposable foam eartips, designed to fit infants, children, and adults.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K081234